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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,461	07/10/2001	Yuan-Tsong Chen	2984.1000-004	6796

21005 7590 06/14/2002

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/902,461	Applicant(s) CHEN, YUAN-TSONG	
	Examiner Michael V. Meller	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 16 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 00/34451.

Human acid alpha glucosidase is administered to a patient to treat Pompe's disease, see abstract, pages 3, 4.

It is noted that since the enzyme is being administered to an individual that it is inherent to that individual that they would suffer from the types of diseases claimed in claims 2-4 since the individuals are not defined in claim 1 as suffering from those specific types of diseases.

Claims 1-4, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by de Barsy et al. (ref. AU2)

Human acid alpha glucosidase is administered to a patient to treat Pompe's disease, see abstract, pages 186.

It is noted that since the enzyme is being administered to an individual that it is inherent to that individual that they would suffer from the types of diseases claimed in claims 2-4 since the individuals are not defined in claim 1 as suffering from those specific types of diseases.

Claims 1-4, 8, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bijvoet et al. (ref. AR2)

Recombinant human acid alpha glucosidase is administered to a patient to treat Pompe's disease, see abstract, pages 1816, 1819, 1821.

It is noted that since the enzyme is being administered to an individual that it is inherent to that individual that they would suffer from the types of diseases claimed in claims 2-4 since the individuals are not defined in claim 1 as suffering from those specific types of diseases.

Claims 1-4, 9, 10, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuller et al. (ref. AV2)

Recombinant precursor form of acid alpha glucosidase is administered to a patient to treat Pompe's disease, see abstract, pages 908.

It is noted that since the enzyme is being administered to an individual that it is inherent to that individual that they would suffer from the types of diseases claimed in

claims 2-4 since the individuals are not defined in claim 1 as suffering from those specific types of diseases.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 11-18, and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over de Barsy et al.

The teachings of the reference are above. The amounts of enzyme used, the method of administration and the intervals at which the enzyme are used are anticipated or in the very least obvious over the cited references. It is not clearly apparent from the reference if these limitations are present or not but it is inherent or in the very least obvious to use the amount, methods of administration and intervals claimed.

Claims 1-4, 8-18, and 21 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 00/34451.

The teachings of the reference are above. The method of administration, the type of enzyme and the intervals at which the enzyme are used are anticipated or in the very least obvious over the cited references. It is not clearly apparent from the reference if

these limitations are present or not but it is inherent or in the very least obvious to use the type of enzyme, methods of administration and intervals claimed.

Claims 1-7, 11-18, and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bijvoet et al. O.K.

The teachings of the reference are above. The amounts of enzyme used, the method of administration and the intervals at which the enzyme are used are anticipated or in the very least obvious over the cited references. It is not clearly apparent from the reference if these limitations are present or not but it is inherent or in the very least obvious to use the amount, methods of administration and intervals claimed.

Claims 1-7, 11-18, and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fuller et al. O.K.

The teachings of the reference are above. The amounts of enzyme used, the method of administration and the intervals at which the enzyme are used are anticipated or in the very least obvious over the cited references. It is not clearly apparent from the reference if these limitations are present or not but it is inherent or in the very least obvious to use the amount, methods of administration and intervals claimed.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Barsy et al. in view of Fuller et al.

The teachings of the reference are above. The reference does not teach that the enzyme is a precursor of recombinant human acid alpha-glucosidase produced in

Chinese hamster ovary cells, the amounts used, the interval used to administer the enzyme, to use an immunosuppressant or that instructions are included with the enzyme for administration.

Fuller teaches that the claimed enzyme can be produced in hamster ovary cells.

It would have been obvious that the enzyme is a precursor of recombinant human acid alpha-glucosidase and that Chinese hamster ovary cells were used to produce the claimed enzyme since Fuller teaches that the claimed enzyme can be produced in hamster ovary cells and that the enzyme is a precursor of recombinant human acid alpha-glucosidase since such desirable results are obtained with such an enzyme. Further, it would have been obvious to use an immunosuppressant since such medications are commonly used to suppress the immune system to better administer drugs and the like, reducing the possibility of rejection of the drug by the immune system. To include instructions in with the enzyme is obvious since the enzyme is going to be used for the same purpose as claimed (as taught by the references) thus one would want to know how to administer the enzyme.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the enzyme beneficially taught by the cited references, the interval the enzymes are administered, the method of administration of the enzyme, etc., especially within the broad ranges instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/34451 in view of Fuller et al.

The teachings of the reference are above. The reference does not teach that the enzyme is a precursor of recombinant human acid alpha-glucosidase produced in Chinese hamster ovary cells, all of the amounts used, the interval used to administer the enzyme, to use an immunosuppressant or that instructions are included with the enzyme for administration.

Fuller teaches that the claimed enzyme can be produced in hamster ovary cells.

It would have been obvious that the enzyme is a precursor of recombinant human acid alpha-glucosidase and that Chinese hamster ovary cells were used to produce the claimed enzyme since Fuller teaches that the claimed enzyme can be produced in hamster ovary cells and that the enzyme is a precursor of recombinant human acid alpha-glucosidase since such desirable results are obtained with such an enzyme. Further, it would have been obvious to use an immunosuppressant since such medications are commonly used to suppress the immune system to better administer drugs and the like, reducing the possibility of rejection of the drug by the immune system. To include instructions in with the enzyme is obvious since the enzyme is going to be used for the same purpose as claimed (as taught by the references) thus one would want to know how to administer the enzyme.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the enzyme beneficially taught by the cited references, the interval the enzymes are administered, the method of administration of the enzyme, etc., especially within the broad ranges instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bijvoet et al. in view of Fuller et al.

The teachings of the reference are above. The reference does not teach that the enzyme is a precursor of recombinant human acid alpha-glucosidase produced in Chinese hamster ovary cells, the amounts used, the interval used to administer the enzyme, to use an immunosuppressant or that instructions are included with the enzyme for administration.

Fuller teaches that the claimed enzyme can be produced in hamster ovary cells.

It would have been obvious that the enzyme is a precursor of recombinant human acid alpha-glucosidase and that Chinese hamster ovary cells were used to produce the claimed enzyme since Fuller teaches that the claimed enzyme can be produced in hamster ovary cells and that the enzyme is a precursor of recombinant human acid alpha-glucosidase since such desirable results are obtained with such an

enzyme. Further, it would have been obvious to use an immunosuppressant since such medications are commonly used to suppress the immune system to better administer drugs and the like, reducing the possibility of rejection of the drug by the immune system. To include instructions in with the enzyme is obvious since the enzyme is going to be used for the same purpose as claimed (as taught by the references) thus one would want to know how to administer the enzyme.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the enzyme beneficially taught by the cited references, the interval the enzymes are administered, the method of administration of the enzyme, etc., especially within the broad ranges instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuller et al. K.

The teachings of the reference are above. The reference does not teach the specific amounts of the enzyme used, the interval used to administer the enzyme, to use an immunosuppressant or that instructions are included with the enzyme for administration.

It would have been obvious to use an immunosuppressant since such medications are commonly used to suppress the immune system to better administer drugs and the like, reducing the possibility of rejection of the drug by the immune system. To include instructions in with the enzyme is obvious since the enzyme is going to be used for the same purpose as claimed (as taught by the references) thus one would want to know how to administer the enzyme.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the enzyme beneficially taught by the cited references, the interval the enzymes are administered, the method of administration of the enzyme, etc., especially within the broad ranges instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller
Examiner
Art Unit 1651

MVM
June 6, 2002